



ATTORNEY'S DOCKET No.: 2003080-0054 (SK-893-US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Danishefsky *et al.* Examiner : Canella, Karen A.
Serial No. : 09/641,742 Art Unit : 1642
Filed : August 18, 2000
For : *Novel Glycoconjugates, Glycoamino Acids, Intermediates Thereto, and Uses Thereof*

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

Sir:

AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

This Amendment and Response to Restriction Requirement is submitted in response to the Office Action mailed on February 12, 2002 for the above-identified application. Applicants request a one (1) month extension of time, from March 12, 2002 to and including April 12, 2002, to reply to the Office Action. With the extension, the deadline for response to the Office Action is April 12, 2002, and thus Applicants respectfully submit that the filing of this response on April 12, 2002 is timely.

1) Response to Restriction Requirement:

As set forth in the Office Action, restriction to one of Groups I, II or III is required. Applicants elect without traverse Group II, directed to claims 27-32 and 39, in part, drawn to multi-antigenic glycopeptides, classified in class 530, subclass 395. In addition, Applicants explicitly reserve the right to pursue any or all of the claims in Groups I and/or III in continuation or divisional applications.

2) Amendments to the specification:

Please replace the paragraph

(i) on page 6 starting at line 12 and ending at line 20; and

(ii) on page 28 starting at line 22 and ending at line 30;

with the following amended paragraph:

In certain preferred embodiments of the present invention, R is allyl, n is 2 and thus the

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inventive compound is a n-pentenyl moiety. In certain other embodiments of the present invention, R is NHR^m, and the protein R^m is KLH or Bovine Serum Albumin. In still other embodiments of the present invention, R is NHR^m, and the lipid R^m is PamCys. It will be appreciated that the protein or lipid can be linked to N directly or through a crosslinker, and thus R^m incorporates proteins, peptides, and lipids, as well as (crosslinker-protein), (crosslinker-peptide) and (crosslinker-lipid) moieties. In certain preferred embodiments, the crosslinker is MMCCH (4-(maleimidomethyl) cyclohexane-1-carboxyl hydrazide).

Please replace the paragraph on page 39 starting at line 11 and ending at line 22 with the following amended paragraph:

This method of treatment comprises administering to the subject a therapeutically effective amount of any of the glycoconjugates disclosed herein, optionally in combination with a pharmaceutically acceptable carrier. The method may be applied wherein the cancer is a solid tumor or an epithelial tumor. As mentioned above, methods for the treatment of cancer (preferably for the prevention of recurrence of cancer) are provided, as well as methods for inducing antibodies in a human subject, wherein the antibodies are capable of specifically binding with human tumor cells, which comprises administering to the subject an amount of any of the glycoconjugates disclosed above effective to induce antibodies. In certain embodiments, the carbohydrate antigen is linked to an effective carrier either directly or through a crosslinker, which carrier is a protein or lipid. In certain embodiments, the carrier protein is bovine serum albumin, polylysine or KLH. In certain other embodiments, the lipid is PamCys.

Please replace the paragraph on page 43 starting at line 17 and ending at line 24 with the following amended paragraph:

wherein n is 0-8; wherein the carrier is a protein or lipid, including, but not limited to Bovine Serum Albumin, KLH and PamCys, wherein said protein or lipid is linked directly or through a crosslinker; and wherein m is in the range of 20-600. In certain preferred embodiments, n is 4. In certain other embodiments, m is in the range of 200-600. In still other preferred embodiments, the carbohydrate determinant is selected from the group consisting of Globo-H, KH-1, glycophorin, STN, (2,3)ST, N3, Tn, TF, 2,6-STn, and Le^y. In yet other preferred embodiments, the carbohydrate determinant is fucosyl GM1, which has the structure as depicted above, and as shown in Figure 1.